Specialty Independent Review Organization

Date notice sent to all parties: 12/14/2015

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE:
The item in dispute is the prospective medical necessity of Norco 10/325mg #120.

A DESCRIPTION OF THE QUALIFICATIONS FOR EACH PHYSICIAN OR OTHER HEALTH CARE PROVIDER WHO REVIEWED THE DECISION:
The reviewer is a Medical Doctor who is board certified in Anesthesiology.

REVIEW OUTCOME:

Upon independent review, the reviewer finds that the previous adverse determination/adverse determinations should be:

☒ Upheld (Agree)

☐ Overturned (Disagree)

☐ Partially Overturned (Agree in part/Disagree in part)

The reviewer agrees with the previous adverse determination regarding the prospective medical necessity of Norco 10/325mg #120.

A copy of the ODG was not provided by the Carrier or URA for this review.

PATIENT CLINICAL HISTORY [SUMMARY]:
The patient is an employee who sustained an injury while lifting heavy boxes on XX/XX/XX. The patient had sharp, aching, and dull pain in the lower back and right leg. The patient was seen and referred to a spine specialist. performed a right L4-5 interlaminar epidural steroid injections on XX/XX/XX. saw the patient on XX/XX/XX. Claimant continues to complain of numbness and radiating pain in right leg.

ANALYSIS AND EXPLANATION OF THE DECISION INCLUDE CLINICAL BASIS, FINDINGS, AND CONCLUSIONS USED TO SUPPORT THE DECISION:
ODG recommends that ongoing use of opioids require ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported

pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patients decreased pain, increased level of function, or improve quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. Four A's for ongoing monitoring: domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: side effects, physical and psychosocial functioning, pain relief, occurrence of any potentially aberrant (or non-adherent) drug related behaviors. These domains have been summarized as the four A's: analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors. This claimant continues to complain of pain despite the use of medications. There is an absence of documentation indicating the claimant has clinically significant functional improvement with this medication, this medication significantly improves psychosocial functioning, these improvements are quantifiable and the claimant is being monitored as required. Therefore, the medical necessity of this request is not established. Although the medication is not medically necessary, this medication should not be stopped abruptly but rather a weaning process may be indicated.

ODG Pain (updated 09/08/15) – Online Version
Opioids, specific drug list
Recommend specific dosage and cautions below. See also Opioids for overall classifications.
Hydrocodone/Acetaminophen
Hydrocodone is a semi-synthetic opioid which is considered the most potent oral opioid that does not require special documentation for prescribing in some states (not including California).
See Opioids Both of these medications refer the reader to "Opioids" in the Official Disability Guidelines.

Below are applicable sections from the Official Disability Guidelines for Opioids:
Recommendations for general conditions:
Neuropathic pain: Opioids have been suggested for neuropathic pain that has not responded to first-line recommendations (antidepressants, anticonvulsants). There are no trials of long-term use. There are virtually no studies of opioids for treatment of chronic lumbar root pain with resultant neuropathy. See Opioids for neuropathic pain.

Chronic back pain: Appears to be efficacious but limited for short-term pain relief, and long-term efficacy is unclear (>16 weeks), but also appears limited. Failure to respond to a time-limited course of opioids has led to the suggestion of reassessment and consideration of alternative therapy. There is no evidence to recommend one opioid over another. In patients taking opioids for back pain, the prevalence of lifetime substance use disorders has ranged from 36% to 56% (a statistic limited by poor study design). Limited information indicated that up to

one-fourth of patients who receive opioids exhibit aberrant medication-taking behavior (Martell-Annals, 2007) (Chou, 2007). There are three studies comparing Tramadol to placebo that have reported pain relief, but this increase did not necessarily improve function (Deshpande, 2007).

Mechanical and compressive etiologies: rarely beneficial. 2

Chronic pain can have a mixed physiologic etiology of both neuropathic and nociceptive components. In most cases, analgesic treatment should begin with acetaminophen, aspirin, and NSAIDs (as suggested by the WHO step-wise algorithm). When these drugs do not satisfactorily reduce pain, opioids for moderate to moderately severe pain may be added to (not substituted for) the less efficacious drugs. A major concern about the use of opioids for chronic pain is that most randomized controlled trials have been limited to a short-term period (less than or equal to 70 days). This leads to a concern about confounding issues such as tolerance, opioid-induced hyperalgesia, long-range adverse effects such as hypogonadism and/or opioid abuse, and the influence of placebo as a variable for treatment effect (Ballantyne, 2006) (Furlan, 2006).

Long-term, observational studies have found that treatment with opioids tends to provide improvement in function and minimal risk of addiction, but many of these studies include a high dropout rate (56% in a 2004 meta-analysis), (Kalso, 2004). There is also no evidence that opioids showed long-term benefit or improvement in function when used as treatment for chronic back pain (Martell-Annals, 2007).

Current studies suggest that the “upper limit of normal” for opioids prior to evaluation with a pain specialist for the need for possible continuation of treatment, escalation of dose, or possible weaning, is in a range from 120-180 mg morphine equivalents a day (Ballantyne, 2006), (AMDG, 2007). There are several proposed guidelines for the use of opioids for chronic nonmalignant pain, but these have not been evaluated in clinical practice, and selection of the patient that will best respond to this treatment modality remains difficult (Nicholas, 2006), (Stein, 2000).

One of the most recent of these guidelines is the Agency Medical Director’s Group (AMDG) Guidelines from Washington State. This guideline includes an opioid dosing calculator (AMDG, 2007).
Outcomes measures: It is now suggested that rather than simply focus on pain severity, improvements in a wide range of outcomes should be evaluated, including measures of functioning, appropriate medication use, and side effects. Measures of pain assessment that allow for evaluation of the efficacy of opioids and whether their use should be maintained include the following: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts (Nicholas, 2006) (Ballantyne, 2006).

A recent epidemiologic study found that opioid treatment for chronic non-malignant pain did not seem to fulfill any of key outcome goals including pain relief, improved quality of life, and/or improved functional capacity (Eriksen, 2006).
Tolerance and addiction: Opioid tolerance develops with the repeated use of opioids and brings about the need to increase the dose and may lead to sensitization. It is now clear that analgesia may not occur with open-ended escalation of opioids. It has also become apparent that analgesia is not always sustained over time, and that pain may be improved with weaning of opioids. (Ballantyne, 2006) (Ballantyne, 2003) See Substance abuse (tolerance, dependence, addiction).
Behavior reinforcement: A major concern in the use of opioids has been that a focus on this treatment without coordination with other modalities, such as psychosocial or behavioral therapy, may simply reinforce pain-related behavior, ultimately undermining rehabilitation that has been targeted at functional 3 restoration (Ontario, 2000). It has been shown that pain behavior can be reinforced by the prescribing of opioids, generally on an unintentional basis by the patient (Fordyce, 1991).
Overall treatment suggestions: Current guidelines suggest the following: - A trial of opioids as a first step in treatment, and the steps involved are outlined in the Criteria for Use of Opioids. The trial includes an initiation phase that involves selection of the opioid and initial dose. (VA/DoD, 2003) - There is then a titration phase that includes dose adjustment. At this phase it may be determined that opioids are not achieving the desired outcomes, and they should be discontinued. - The final stage is the maintenance phase. If pain worsens during this phase the differential to evaluate includes disease progression, increased activity, and/or new or increased pre-existing psychosocial factors that influence pain. In addition, the patient may develop hyperalgesia, tolerance, dependence or actual addiction (Washington, 2002) (Colorado, 2002) (Ontario, 2000) (VA/DoD, 2003) (MaddoxAAPM/APS, 1997) (Wisconsin, 2004) (Warfield, 2004). See Substance abuse (tolerance, dependence, addiction). See also Implantable pumps for narcotics. See also Opioids in the Low Back Chapter. See Criteria for Use of Opioids.

The applicable sections of the Official Disability Guidelines for continued use of opioids is the following:
4) On-Going Management. Actions Should Include:
(a) Prescriptions from a single practitioner taken as directed, and all prescriptions from a single pharmacy.
(b) The lowest possible dose should be prescribed to improve pain and function.
(c) Office: Ongoing review and documentation of pain relief, functional status, appropriate medication use, and side effects. Pain assessment should include: current pain; the least reported pain over the period since last assessment; average pain; intensity of pain after taking the opioid; how long it takes for pain relief; and how long pain relief lasts. Satisfactory response to treatment may be indicated by the patient's decreased pain, increased level of function, or

improved quality of life. Information from family members or other caregivers should be considered in determining the patient's response to treatment. Four domains have been proposed as most relevant for ongoing monitoring of chronic pain patients on opioids: pain relief, side effects, physical and psychosocial functioning, and the occurrence of any potentially aberrant (or non-adherent) drug-related behaviors. These domains have been summarized as the "4 A's" (analgesia, activities of daily living, adverse side effects, and aberrant drug-taking behaviors). The monitoring of these outcomes over time should affect therapeutic decisions and provide a framework for documentation of the clinical use of these controlled drugs (Passik, 2000).
(d) Home: To aid in pain and functioning assessment, the patient should be requested to keep a pain dairy that includes entries such as pain triggers, and incidence of end-of-dose pain. It should be emphasized that using this diary will help in tailoring the opioid dose. This should not be a requirement for pain management.
(e) Use of drug screening or inpatient treatment with issues of abuse, addiction, or poor pain control (Webster, 2008).
(f) Documentation of misuse of medications (doctor-shopping, uncontrolled drug escalation, drug diversion).
(g) Continuing review of overall situation with regard to non-opioid means of pain control.
(h) Consideration of a consultation with a multidisciplinary pain clinic if doses of opioids are required beyond what is usually required for the condition or pain does not improve on opioids in 3 months. Consider a psych consult if there is evidence of depression, anxiety or irritability. Consider an addiction medicine consult if there is evidence of substance misuse (Sullivan, 2006) (Sullivan, 2005) (Wilsey, 2008) (Savage, 2008) (Ballyantyne, 2007).

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:

- ☐ **ACOEM- AMERICAN COLLEGE OF OCCUPATIONAL & ENVIRONMENTAL MEDICINE UM KNOWLEDGEBASE**
- ☐ **AHCPR- AGENCY FOR HEALTHCARE RESEARCH & QUALITY GUIDELINES**
- ☐ **DWC- DIVISION OF WORKERS COMPENSATION POLICIES OR GUIDELINES**
- ☐ **EUROPEAN GUIDELINES FOR MANAGEMENT OF CHRONIC LOW BACK PAIN**
- ☐ **INTERQUAL CRITERIA**
- ☒ **MEDICAL JUDGEMENT, CLINICAL EXPERIENCE, AND EXPERTISE IN ACCORDANCE WITH ACCEPTED MEDICAL STANDARDS**
- ☐ **MERCY CENTER CONSENSUS CONFERENCE GUIDELINES**
- ☐ **MILLIMAN CARE GUIDELINES**
- ☒ **ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**
- ☐ **PRESSLEY REED, THE MEDICAL DISABILITY ADVISOR**
- ☐ **TEXAS GUIDELINES FOR CHIROPRACTIC QUALITY ASSURANCE & PRACTICE PARAMETERS**
- ☐ **TEXAS TACADA GUIDELINES**
- ☐ **TMF SCREENING CRITERIA MANUAL**
- ☐ **PEER REVIEWED NATIONALLY ACCEPTED MEDICAL LITERATURE (PROVIDE A DESCRIPTION)**
- ☐ **OTHER EVIDENCE BASED, SCIENTIFICALLY VALID, OUTCOME FOCUSED GUIDELINES (PROVIDE A DESCRIPTION)**